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October 9, 2012

VIA ECF

The Honorable Paul S. Diamond
United States District Judge
Eastern District of Pennsylvania
601 Market Street
Philadelphia, PA 19106-1723

Re: *Mylan Pharmaceuticals, Inc. v. Warner Chilcott et al.*
Civ. No. 12-3824 (Consolidated)

On July 6, 2012, Mylan filed a Complaint against Warner Chilcott and Mayne ("Defendants") for violations of federal antitrust law and state common law. In essence, the Complaint contains 119-paragraphs of detailed, factual allegations explaining how Defendants' "anti-generic strategy" harmed consumers of Doryx, and Mylan, by suppressing competition from lower-priced generic versions of Doryx.

On October 1, 2012, Defendants' moved to dismiss Mylan's Complaint.[1] Despite submitting 80-pages of briefing in support of their motions, Defendants' positions can be boiled down to three simple arguments: (1) Mylan fails to state a claim under the Sherman Act; (2) even if it does, Defendants' conduct is protected by the *Noerr-Pennington* doctrine and falls outside the statute of limitations; and (3) Mylan fails to state a claim for tortious interference under state law. Pursuant to the Court's October 5, 2012 Order, Mylan respectfully submits a preliminary response to these arguments, and will file a formal opposition brief on November 15, 2012 per the schedule set forth in the Court's August 24, 2012 Case Management Order.

I. Mylan States a Claim Under Section 2 of the Sherman Act

Monopolization requires proof of two elements: (A) exclusionary conduct; and (B) monopoly power. Mylan has pled both.

[1] Defendants' motions to dismiss include numerous references to evidence that is neither cited nor relied upon in the Complaint. As a general rule, evidence extrinsic to the complaint may not be considered by a court ruling on a motion to dismiss, unless it falls into the limited exception for "documents that are 'integral to or explicitly relied upon in the complaint.'" *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F. 3d 85, 97 n.6 (3d Cir. 2010) (citation omitted), *cert. denied*, 132 S. Ct. 98 (2011).

A. Exclusionary Conduct

Mylan alleges that Defendants' self-proclaimed "anti-generic strategy" with respect to Doryx was exclusionary. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007). Anticipating lower-priced generic competition, Defendants (1) reformulated (but did not improve) Doryx, (2) "swap[ped] out" the existing formulation for the reformulated product, and then (3) discontinued the existing formulation solely to impede generic substitution. Remarkably, Defendants' switched the market *three* separate times—first, swapping out *capsules for tablets*; next, swapping out *75 and 100 mg tablets for 150 mg tablets*; and, finally, swapping out *150 mg single-scored tablets for 150 mg dual-scored tablets*. Compl. ¶¶ 52-72. But for Mylan's ultimate entry on the 150 mg tablet, Defendants had plans to switch the market to a *fourth* formulation. *Id.* at ¶¶ 73-75.

Defendants argue that their "anti-generic strategy" simply avoids free-riding and, therefore, cannot constitute exclusionary conduct. What Defendants' term as "free-riding," however, is precisely how generic competition is intended to operate under federal and state law. The Hatch-Waxman Act—passed by Congress in 1984 and designed to balance the public's interest in access to low-cost generic drugs with patentees' interest in maintaining their patent rights—expedites the FDA approval process for generic drugs. *Id.* at ¶¶ 21-22. Rather than conduct full clinical trials, a generic manufacturer may submit an Abbreviated New Drug Application (ANDA) demonstrating that its drug is bioequivalent to the reference listed drug. *Id.* at ¶ 22. Once approved, the generic is deemed "AB-rated" to the reference listed drug, allowing (and sometimes mandating) pharmacists to substitute the generic when presented with a prescription for the brand under state law. *Id.*

Defendants' "anti-generic strategy" has been effective in suppressing generic competition by intentionally subverting this process. Because a generic drug must be the same dosage form and strength as the branded drug to be AB-rated, a change in the dosage form or strength of the brand product prevents an AB-rating, thereby defeating generic substitution. *Id.* Thus, when Defendants change the *form* of Doryx from a capsule to a tablet, "swap-out" capsules for tablets, and then remove capsules from the market, they prevent generic substitution for Doryx as generic capsules are not AB-rated to branded tablets, and branded capsules no longer exist. *Id.* at ¶¶ 33, 52-60. Similarly, when Defendants' change the *strength* of Doryx from 75 and 100 mg to 150 mg tablets, "swap-out" 150 mg tablets for 75 and 100 mg tablets, and then remove 75 and 100 mg tablets from the market, they prevent generic substitution for Doryx as generic 75 and 100 mg tablets are not AB-rated to branded 150 mg tablets, and branded 75 and 100 mg tablets no longer exist. *Id.* at ¶¶ 33, 61-64. Defendants' lather, rinse, repeat formula forces a generic manufacturer to re-start the ANDA approval process and, in the meantime, denies consumers the benefit of lower-priced generic competition to Doryx.[2] As the leading treatise on the intersection of antitrust and intellectual property succinctly describes:

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[2] Notably, Defendant Warner Chilcott's argument that product hopping is not anticompetitive is contrary to its own experience. Indeed, the FTC investigated and filed a complaint against Warner Chilcott related to a similar strategy to "switch" the market from a non-chewable to a chewable form of one of its oral contraceptive products in order to maintain its monopoly position and prevent generic entry. *See FTC v. Warner Chilcott Corp.*, No. 1:05-cv-02179,

> The generic firm may, of course, continue to offer the first drug, for which it already gained approval. That means little, however, if the branded firm has pulled that drug from pharmacy shelves and convinced doctors to write prescriptions for its new product. Until the ANDA for that new product is approved (with its AB-rating), state laws limit the ability of pharmacists to substitute the "old" generic for the "new" branded drug.

HERBERT HOVENKAMP, ET AL., IP & ANTITRUST § 15.3c1 (2d ed. 2011) (hereinafter, "IP & ANTITRUST").

Far from condoning Defendants' conduct as simply the avoidance of free-ridership, the IP & ANTITRUST treatise concludes that "product hopping to ward off generic competition is precisely the sort of behavior the Sherman Act condemns." *Id.* Likewise, the only court to have considered facts similar to those alleged here found that foreclosure of generic substitution through "allegedly manipulative and unjustifiable formulation changes" coupled with the removal of the old formulations from the market, if proven, would constitute anticompetitive conduct. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 423 (D. Del. 2006) ("*TriCor*") ("Competitors need not be barred 'from all means of distribution,' if they are barred 'from the cost-efficient ones.'") (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001) (en banc)). And, while monopolists have no general duty to aid competitors, "they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition." IP & ANTITRUST § 15.3c1 (citing *United States v. Grinnell*, 384 U.S. 563, 571 (1966) (condemning behavior that "was done plainly and explicitly for a single purpose" of driving out competitors)).

Notwithstanding their conduct to defeat generic competition to Doryx through their multiple product "swap-outs," Defendants also invoke innovation in defense of their exclusionary conduct. As an initial matter, Defendants' claim that their Doryx reformulations were product improvements directly—and impermissibly—contradicts Mylan's Complaint. Indeed, Mylan alleges the opposite: that each switch "provided little or no benefit other than to exclude generic competition from the market." Compl. ¶¶ 55, 64, 72. Moreover, Defendants' after-the-fact arguments in support of their motions are at odds with their own contemporaneous business documents. For example, according to Defendants, "[t]hey [did] not expect to have any increase in sales as part of the switch [from capsules to tablets]," rather it was "merely [] an anti-generic strategy." Compl. ¶ 3; *see id.* ¶ 49 (that "[i]t is [Warner Chilcott's] intention to discontinue the Doryx capsule as soon as the tablet is available to eliminate generic competition."). Finally, the determination of whether Defendants' multiple product "swap-outs" are exclusionary is properly evaluated under the rule of reason. *See Microsoft*, 253 F.3d at 65 (applying a fact bound rule of reason; "[j]udicial deference to product innovation … does not mean that a monopolist's product design decisions are *per se* lawful."); *TriCor*, 432 F. Supp. 2d

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Dkt. No. 1, at ¶¶ 39-40 (D.D.C. Nov. 7, 2005) (Complaint for Injunctive and Other Equitable Relief). Warner Chilcott ultimately agreed to a stipulated permanent injunction prohibiting it from engaging in switching strategies with the subject product. *See id*. Dkt. No. 90, at 8 (D.D.C. Oct. 23, 2006) (Final Order and Stipulated Permanent Injunction).

at 422 ("[A]s in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants").

Mylan's Complaint clearly alleges anticompetitive effects from Defendants' product switching that are not offset by any plausible justification. Specifically, Mylan alleges that, as a result of Defendants' anticompetitive conduct, consumers and federal, state, and private payors have been forced to overspend on prescriptions for delayed-release doxycycline hyclate products and have been denied the substantial benefits of lower-priced generic competition to Doryx. Compl. ¶ 9. Moreover, by discontinuing its existing formulations of the drug as part of its "swap-out" scheme, Defendants' conduct has precluded and/or reduced, rather than expanded, consumer choice. *Id.* ¶ 82. Indeed, this reduction in consumer choice was critical to the court's analysis in *TriCor*:

> The per se standard proposed by Defendants presupposes an open market where the merits of any new product can be tested by unfettered consumer choice. But here, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations.

TriCor, 432 F. Supp. 2d at 422. This rationale was also essential to the court's decision in *Walgreen*—a case in which AstraZeneca introduced Nexium, but *did not* remove Prilosec from the market or seek to prohibit generic substitution of Prilosec. *Walgreen Co. v. AstraZeneca Pharms. LP*, 534 F. Supp. 2d 146 (D.D.C. 2008). In granting defendant's motion to dismiss in that case, the court distinguished *TriCor* on the facts, explaining:

> The elimination of choice was a critical factor in the court's decision to deny Abbott's motion to dismiss the complaint. … Yet, here, there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices. It introduced a new drug to compete with already-established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs.

Id. at 151.[3] Because Defendants here reduced, rather than enhanced, competitive alternatives to Doryx—both by removing prior formulations of the drug as well as suppressing lower-priced generic competition to Doryx by impeding generic substitution—Mylan alleges Defendants' conduct resulted in anticompetitive effects.

Conversely, while Mylan alleges anticompetitive effects from Defendants' "anti-generic strategy," it also alleges that this scheme provided no offsetting procompetitive benefits. *See, e.g.*, Compl. ¶¶ 2, 9, 55, 64, 72, 82. The sole purpose, instead, of removing its products from the market (repeatedly) was to preclude generic competition. *Id.* ¶¶ 55, 64, 72. Mylan's detailed

[3] *AstraZeneca AB v. Mylan Labs. Inc.* challenges the exact same conduct at issue in *Walgreen*, and is distinguishable on the same basis. 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010), *aff'd*, Fed. Appx. 297 (Fed. Cir. 2011).

allegations of Defendants' exclusionary conduct plainly raise a sufficient inference of a right to relief to survive a motion to dismiss. *See West Penn*, 627 F.3d at 98 ("We conclude that it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases."); *In re OSB Antitrust Litig.*, 2007 WL 2253419, at *1 (E.D. Pa. Aug. 3, 2007) ("Plaintiffs have made specific factual allegations of Defendants' wrongdoing. . . . *Twombly* requires no more.").

B. Monopoly Power

Monopoly power is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). It can be proven through two methods: (1) direct evidence of power to control prices or exclude competition, or (2) indirect evidence such as the defendant's share of the relevant market and the existence of barriers to entry. *Broadcom*, 501 F.3d at 307. Defendants' motions to dismiss do not even address direct evidence of monopoly power. Thus, Defendants' claim that Mylan has failed to adequately allege a relevant market is not only incorrect; it is also insufficient to establish that the Complaint is deficient on the ultimate issue of adequately alleging monopoly power, since direct evidence of monopoly power does not require market definition. *Id.* at 307 n.3. Mylan has sufficiently set forth facts to demonstrate monopoly power through both direct and indirect evidence.

Direct evidence. As the Supreme Court explained, "[s]ince the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (quoting 7 P. AREEDA, ANTITRUST LAW ¶ 1511, at 429 (1986)); *Broadcom*, 501 F.3d at 307.

Defendants' product hopping activities had the actual effect of excluding competition. These strategies inhibited Mylan from bringing a competing generic version of Doryx to market through the most efficient channel of distribution. Compl. ¶ 78. Likewise, Defendants' conduct allowed them to control prices, maintaining Doryx's price levels without the price reductions (or lost sales) that Defendants knew would result if generics began to compete. *Id.* ¶ 81. These facts suffice to show Defendants' actual exercise of market power. *See Toys "R" Us v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (direct evidence of market power where the defendant "was remarkably successful in causing the 10 major toy manufacturers to reduce output of toys to the warehouse clubs, and that reduction in output protected [the defendant] from having to lower its prices to meet the clubs' price levels.").

Indirect evidence. While Mylan's pleadings on direct evidence satisfy the pleading standard for monopoly power, the Complaint also sufficiently pleads facts to support an inference through indirect evidence. A plaintiff may demonstrate defendants' market power through indirect proof, *i.e.*, proof of a high share of the "relevant market," accompanied by significant barriers to entry into that market. *Broadcom*, 501 F.3d at 307. Here, Defendants have held a 90-100% share of the alleged market for several years, and regulatory and technological barriers undeniably make entry by new competitors extremely difficult. *See* Compl. ¶¶ 39-40. Defendants therefore limit their motion to the relevant markets Mylan alleges,

"the Doxycycline Hyclate market," and various submarkets. They claim Mylan has failed to define a relevant market, despite eleven full paragraphs devoted to the issue in the Complaint. *See id*. ¶¶ 30-40.

Defendants' own conduct proves Mylan's market definition. A relevant market is based primary on cross-elasticity of demand and, thus, is comprised here only of those products that provide a significant constraint on Doryx prices. ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 577-80 (7th ed. 2012) (citing several cases); ABA SECTION OF ANTITRUST LAW, MARKET DEFINITION IN ANTITRUST 8-10 (2012). As alleged in the Complaint, Defendants knew that products other than delayed-release doxycycline hyclate were not reasonable substitutes constraining Doryx pricing. Had they been constraints, Doryx prices would already have been at competitive levels and there would be no reason to engage in an anti-generic strategy because the entry of generics would not have added significantly to the constraint other products would have been providing. Instead, viewing generic competition as the closest competitive substitute to branded Doryx, Defendants engaged in an extensive "anti-generic strategy" spanning three separate product switches and other conduct designed to "buy time" to effectuate the switches. Defendants recognized that competing against a generic version of Doryx constrains the price of branded Doryx in a way that competition with other branded products simply does not. Without more, that is proof (or, here, allegations) enough that the market consists of Doryx and its generic variants, not the various other products which offer little competitive constraint.

In the context of the pharmaceutical industry, courts have found the existence of well-defined markets consisting of the branded drug and its generic equivalents only.[4] *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (finding that relevant market is limited to ciprofloxacin and does not include competing branded antibiotics), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003).

Mylan has here alleged facts showing that the relevant product market comprises various formulations of Doryx and their AB-rated generic equivalents as well as the overall delayed-release doxycycline hyclate market. Compl. ¶¶ 36-37. The unique dynamics of prescription medication markets make it entirely plausible—and, in fact, routine—for a single medication to constitute an independent antitrust market, even when other medications treat similar conditions. Here, delayed-release doxycycline hyclate is labeled for use in the treatment of severe acne, which by definition is acne that is non-responsive to over-the-counter treatments or less drastic prescription treatments. The sort of severe, cystic acne for which systemic treatments are indicated cannot be treated by "wipes" or other routine interventions, so excluding them from the market makes perfect sense. Likewise, in light of the lack of head-to-head studies comparing

[4] Some courts have defined the market even more narrowly in the context of pharmaceuticals, concluding that the branded and generic versions of the *very same* drug constituted separate product markets for antitrust purposes. *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496-99 (2d Cir. 2004) (concluding that generic warfarin sodium constituted its own relevant market, and branded warfarin sodium should not be included).

delayed-release doxycycline hyclate to other possible oral antibiotics, physicians will presumably prescribe the medication they are most comfortable using, without regard to cost. *See FTC v. Lundbeck*, 650 F.3d 1236, 1240 (8th Cir. 2011).

Furthermore, the relevant market is a highly factual inquiry, the sufficiency of which is most appropriately evaluated at the summary judgment or trial stage. *See Newcal Indus. v. IKON Office Solution*, 513 F.3d 1038, 1045 (9th Cir. 2008) (noting that validity of the relevant market is typically a factual element rather than a legal element); *Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) (recognizing that "[b]ecause market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market."). Courts in the Third Circuit have also taken note of the highly factual nature of evaluating the boundaries of the relevant market. "The relevant market element of an antitrust claim 'can be determined only after a factual inquiry into the commercial realities' of the market." *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 547 (D.N.J. 2000) (quoting *Eastman Kodak Co. v. Image Tech. Servs., Inc*., 504 U.S. 451, 482 (1992)). *Queen City Pizza, Inc. v. Domino's Pizza, Inc*., 124 F.3d 430, 436 (3d Cir. 1997) is not at all contrary. It recognizes that "in most cases, proper market definition can be determined only after a factual inquiry." The allegations there were of a market that was preposterous on its face—wholly unlike the widely acknowledged market definition Mylan alleges here. For the forgoing reasons, Mylan has not only adequately pled a valid relevant market, but more importantly has adequately pled facts supporting monopoly power—through both direct evidence and indirect evidence.

C. Attempted Monopolization

Attempted monopolization requires proof that Defendant (1) engaged in exclusionary conduct, (2) with a specific intent to monopolize, and (3) with a "dangerous probability" of achieving monopoly power. As discussed above, Mylan alleges that Defendants engaged in exclusionary conduct in furtherance of their self-proclaimed "anti-generic strategy" intended solely to foreclose competition from lower-priced generic alternatives. As a result, Defendants have maintained and extended their monopoly power and/or have had a dangerous probability of doing so. Compl. ¶¶ 55, 64, 72, 101-08.

D. Antitrust Injury and Causation

Antitrust injury is defined as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). A plaintiff, like Mylan, that seeks to compete in a market by offering lower prices but is excluded by defendants' conduct plainly incurs antitrust injury. *Hammes v. AAMCO Transmissions, Inc*., 33 F.3d 774, 783 (7th Cir. 1994) (Posner, J.) (excluding plaintiff who "wanted to compete by underselling" defendants incurs antitrust injury); *accord Palmyra Park Hosp. v. Phoebe Putney Mem'l Hosp*., 604 F.3d 1291, 1303 (11th Cir. 2010); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003) ("[T]he anticompetitive effects of exclusion [of generics] cannot be seriously debated"); *Novell, Inc. v. Microsoft Corp*., 505 F.3d 302, 317 (4th Cir. 2007). Moreover, throughout its Complaint, Mylan alleges that its injury flows directly from Defendants' anticompetitive conduct. *See, e.g.*, Compl. ¶¶ 78-86.

II. Mylan States a Claim Under Section 1 of the Sherman Act

A claim under Sherman Act § 1 requires allegations of (a) a "contract, combination, or conspiracy" and (b) an unreasonable restraint of trade. ANTITRUST LAW DEVELOPMENTS 2. Defendants make no argument that Mylan has insufficiently pled the requisite harm to competition needed to satisfy the "unreasonable restraint of trade," the second element under Section 1. They argue only the first element, asserting that Mylan fails to allege more than conclusory allegations of an agreement or conspiracy. However, Mylan has alleged direct evidence of an agreement—Defendants' internal documents and public statements—that Mayne and Warner Chilcott engaged in acts in furtherance of a conspiracy to suppress generic competition. In fact, Mylan's allegations go far beyond what the case law requires. *See West Penn*, 627 F.3d at 98.

Defendants' position that a patent-holder and licensee are legally incapable of conspiring under *Copperweld's* "single entity" is simply incorrect. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984). Contrary to Defendants' reading of *Levi Case Co. v. ATS Prods.*, 788 F. Supp. 428, 431 (N.D. Cal. 1992) (Walker, J.), the case makes clear that a patent holder and its licensee can conspire if the "relationship deprives the marketplace of independent actors." Unlike the alleged conspiracy between Mayne and Warner-Chilcott, *Levi* did not involve an agreement between two independent sources of economic power who were plausibly independent actors in the marketplace. In *Levi*, the court held that an individual was incapable of conspiring with the company he formed, and conveyed his patents to, in order to exploit his patent. Subsequent decisions, including a decision by Judge Walker (who authored *Levi*), have limited *Levi's* holding to its facts. *See e.g.*, *Pecover v. Electronics Arts Inc.*, 633 F. Supp. 2d 976, 983-85 (N.D. Cal. 2009) (Walker, J.) (declining to extend Levi's application of *Copperweld* because a "series of agreements between EA and [the NFL, AFTL and NCAA] could plausibly deprive the marketplace of independent sources of economic power"); *see also Townshend v. Rockwell Int'l Corp.*, 2000 WL 433505, at *6 (N.D. Cal. Mar. 28, 2000).

Defendants also cite *Shionogi Pharma., Inc. v. Mylan, Inc.*, 2011 WL 2174499 (D. Del. May 26, 2011), in which the court dismissed Mylan's Section 1 counterclaims. Unlike *Shionogi*, Mylan's Complaint in this action states detailed non-conclusory facts and sufficiently pleads a Section 1 conspiracy between Mayne and Warner Chilcott. Moreover, the court in *Shionogi* did not engage in the analysis articulated by the Supreme Court's 2010 opinion in *American Needle v. NFL*, 130 S. Ct. 2201 (2010), which both limited and clarified the applicability of *Copperweld*. *American Needle* reinforced that "substance, not form" determines whether an entity is capable of conspiring, and that the fact of a licensing arrangement is not enough to justify single-entity treatment. *Id.* at 2211. Thus, Defendants cannot be entitled to immunity from Section 1 scrutiny under *Copperweld* merely on the basis of a patent-licensing agreement. The key factual inquiry is whether there is a "contract, combination, or conspiracy amongst separate economic actors pursuing economic interests such that the agreement deprives the marketplace of independent centers of decisionmaking and therefore of a diversity of entrepreneurial interests, and thus of actual or potential competition." *Id.* at 2212 (internal marks and citations omitted).

Defendants acknowledge that they are separate and independent specialty pharmaceutical companies. Warner Chilcott Mot. at 4-5. If Defendants' are now claiming they are no longer independent, whether the companies are a capable of conspiring is a factual issue subject to discovery and not appropriate for consideration at the pleading stage of litigation. *See, e.g.*, *Townshend*, 2000 WL 433505, at *6 (declining to dismiss complaint under *Levi* holding because the question of capability to enter a conspiracy is a question of fact).

III. Neither *Noerr* Nor the Federal Statute of Limitations Bars Mylan's Claims

A. *Noerr-Pennington*

The Supreme Court's decision in *Noerr*, 365 U.S. 127 (1961) ("*Noerr*"), serves to protect the rights of private parties to influence government, and when they do so, to be free from antitrust attack. The Court grounded *Noerr* in two objectives, neither of which is implicated in the present case: to protect (1) the Constitutional rights of individuals to petition the government, and (2) the decision making process of the government. *Id.* at 137-38. The *Noerr* safe harbor, therefore, protects parties whose conduct may have anticompetitive effects but are "the *result* of valid governmental action, as opposed to private action" and further explains that no antitrust violation "can be predicated upon *mere* attempts to influence the passage or enforcement of laws." *Id.* at 135-36 (emphasis added).

The present case simply does not fall into the category of activity the Supreme Court sought to protect in *Noerr*. The anticompetitive effects of Defendants' "anti-generic strategy" were not the *result* of valid governmental action or a *mere* attempt to influence government. Rather, Defendants' purely *private actions*, prior and subsequent to FDA approval of their products—product reformulation (without improvement), "swap-out" of the existing formulation for the reformulated product, and discontinuation of the existing formulation solely to impede generic substitution—caused the anticompetitive result. These actions involved no petitioning activity whatsoever and, therefore, are far outside the scope of *Noerr*.

Defendants' briefs cite nothing to support their attempt to expand *Noerr* to stand for the proposition that government approval of a product—here FDA's approval of the multiple versions of Defendants' products as "safe and effective," a review that does not involve any determination of whether a product is better or improved from its prior version—can insulate other, independent private acts *devoid of any government assent or review* that cause anticompetitive results. Just as a government issued driver's license does not authorize the holder to run over his neighbor's mailbox, the FDA's approval of a product for marketing does not authorize and immunize every other act the Defendants take with respect to that product line.

Moreover, Defendants cite no law for an interpretation of *Noerr* that would extend immunity from one potentially protected action to other *entirely private* actions. Precedent is to the contrary. None of the challenged activity here involves any petitioning activity. But even if some did, it remains true that, when an "overall scheme" of anticompetitive behavior includes both *Noerr* protected and unprotected behavior, courts have refused to dismiss plaintiffs' claims. In *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240 (9th Cir. 1982), the Ninth Circuit reversed the lower court holding that an anticompetitive scheme will not

be insulated from antitrust scrutiny just because it includes some *Noerr* protected acts—if the protected acts of petitioning "were part of a larger antitrust conspiracy, the conspiracy is subject to the antitrust laws." *Id.* at 1264 ("It is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute.") (citing *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513-14 (1972)). In rejecting the defendants' arguments, the court noted: "The defendants' actions do not enjoy immunity, even though a part of the actions may have involved protected first amendment petitioning. The reach of the *Noerr-Pennington* doctrine is not that extensive, and the antitrust laws are not that impotent." *Id.* at 1265. *See also Rochester Drug Co-Op., Inc., v. Braintree Labs.*, 712 F. Supp. 2d 308, 320-21 (D. Del. 2010) (denying a motion to dismiss based on *Noerr* refusing to parse out the component parts of the plaintiff's theory which included both protected and unprotected activity).

The *TriCor* decision further supports this conclusion. While not expressly referencing *Noerr*, the court addressed defendants' attempt in that case to immunize their conduct under the First Amendment relying upon *Trucking Unlimited*. Specifically, the court rejected defendants' assertion that their changing "NDDF" codes was commercial speech, finding the defendants' conduct not immunized from antitrust scrutiny when it was "used as an integral part of conduct which violates a valid statute." 432 F. Supp. 2d at 424 (quoting *Trucking Unlimited*, 404 U.S. at 514). The court concluded that "the changes in the NDDF code are alleged to be part of the Defendants' anticompetitive scheme, and those changes are an appropriate part of the circumstances to be considered in this case when evaluating Defendants' allegedly unlawful actions." *Id.* Likewise here, Defendants' reformulation/swap-out/discontinuance recipe for eliminating generic competition to Doryx—and other conduct designed to effectuate these successive product cannibalizations—is not immunized under *Noerr*.

B. Federal Statute of Limitations

Defendants' statute of limitations argument simply misstates and misapplies the law. It ignores entirely the continuing violation doctrine in the context of antitrust law and applicable Third Circuit authority. The only case Defendants cite in support of their argument is a case that addressed the narrow issue of when the statute of limitations applies under the Racketeer Influenced and Corrupt Organizations Act. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 182 (1997). In the context of a continuing violation under Sections 1 and 2 of the Sherman Act, as Mylan has alleged, each time a plaintiff is injured by an act of the defendants, a cause of action accrues and the statute of limitations runs from the commission of the act. *See West Penn*, 627 F.3d at 106-08 (applying continuing violation doctrine to Section 1 claim); *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481, 502 n.15 (1968) (applying the same to Section 2 claim). Mylan has properly alleged a continuing violation in which Defendants committed a series of acts in furtherance of their anticompetitive scheme within the statute of limitations period. Compl. ¶¶ 52-72. Therefore, Mylan's Sherman Act claims are not barred by the statute of limitations.

IV. Mylan States a Claim for Tortious Interference Under State Law

Defendants' argument that the competition privilege precludes Mylan's tortious interference claim has no merit. The competition privilege only applies in "certain circumstances," *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 215 (3d Cir. 2009), and does not apply if a defendant's conduct creates an "unlawful restraint on trade." *InterVest Fin. Servs., Inc. v. S.G. Cowen Sec. Corp.*, 206 F. Supp. 2d 702, 721 (E.D. Pa. 2002), *aff'd sub nom. InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144 (3d Cir. 2003). Because the very essence of Mylan's allegations are that Defendants' conduct created an unlawful restraint on trade, Defendants' claim of the competition privilege is unjustified. *InterVest*, 206 F. Supp. 2d at 721 (recognizing that the same conduct that gives rise to an antitrust violation may also give rise to a tortious interference claim); *see also Babyage.com, Inc. v. Toys "R" Us, Inc.*, 558 F. Supp. 2d 575, 589 (E.D. Pa. 2008) (denying dismissal of antitrust and tortious interference claims).

Mylan has sufficiently alleged facts supporting all elements of a claim for tortious interference of prospective economic advantage under Pennsylvania law. Compl. ¶¶ 109-19. Mylan has alleged: (1) prospective contractual relationships existed between Mylan and its prospective customers; (2) Defendants took purposeful action in order to interfere with Mylan's relationships with prospective customers, through their continued efforts to convert the Relevant Markets to new versions of Doryx on the eve of generic entry and manipulate the FDA regulatory process; (3) no privilege applies; and (4) damages resulted from the Defendants' scheme to prevent, delay, or inhibit generic competition. *See Remick v. Manfredy*, 238 F.3d 248, 263 (3d Cir. 2001).

Defendants' argument that the law requires that Mylan identify each specific customer or contract also fails. *See Marshall v. Fenstermacher*, 388 F. Supp. 2d 536, 557 (E.D. Pa. 2005) (plaintiff asserting a claim for tortious interference need only "allege an expectation, either by contract or otherwise, for economic gain."). In *TriCor*, the court expressly rejected the argument that Plaintiff's complaint must identify the specific relationships that have been disrupted. *See also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 704 (E.D. Pa. 2004) (allegation that SmithKline brought a sham patent infringement suit against Torpharm for the purpose of keeping it out of the generic Paxil market is sufficient to state a tortious interference claim). In the context of claims of tortious acts that prevent, delay, or inhibit generic entry, the interference is with *all* prospective customers of the generic drug. Mylan has alleged such interference. Nothing more is required at this stage.

Finally, the continuing violation doctrine defeats Defendants' state statute of limitations argument. Pennsylvania courts have recognized the continuing tort theory and applied it to intentional tort claims, including intentional interference. *Brillhart v. Sharp*, 2008 WL 2857713, at *5 (M.D. Pa. July 21, 2008); *Dellape v. Murray*, 651 A.2d 638, 640 (Pa. Commw. Ct. 1994). A claim falls within the continuing violations theory if (1) at least one act occurred within the filing period and (2) the claim is more than an occurrence of isolated or sporadic acts. *Brillhart*, 2008 WL 2857713, at *5. Mylan has alleged multiple acts which were part of Defendants' broader scheme to interfere with the sale of generic Doryx products to Mylan's prospective customers, which continued through the first quarter of 2012. Because Mylan has alleged a continuing violation, its tortious interference claims relating to capsules are not barred.

Conclusion

For the foregoing reasons, Defendants' motions to dismiss should be denied in their entirety.

Respectfully Submitted,

Dated: October 9, 2012

WILSON SONSINI GOODRICH & ROSATI
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By: /s/ Seth C. Silber

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* Motion for admission *pro hac vice* submitted today.

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the forgoing to be served this day upon all counsel of record in this proceeding via CM/ECF and electronic mail.

Dated: October 9, 2012

/s/ Seth C. Silber
Seth C. Silber